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PATENT  
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Certificate of Mailing: Date of Deposit: June 26, 2001

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry

Printed name of person mailing correspondence

Susan M. Barry

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Douglas A. Treco et al.

Art Unit: 1636

Serial No.: 09/431,821

Examiner: J. Ketter

Filed: November 2, 1999

Title: Targeted Introduction of DNA into Primary or Secondary Cells and Their  
Use for Gene Therapy and Protein Production

Assistant Commissioner for Patents  
Washington, D.C. 20231

TERMINAL DISCLAIMER UNDER 37 C.F.R. §§ 1.321 and 3.73(b)

Pursuant to 37 C.F.R. § 1.321(b), Transkaryotic Therapies, Inc., the assignee of the entire right, title, and interest in the above-captioned patent application, seeks to disclaim the terminal portion of the term of the patent to be granted on the application. This terminal disclaimer is binding on the grantee and its successors or assigns.

Pursuant to 37 C.F.R. § 1.321(b)(1), this terminal disclaimer is signed by an attorney of record.

Pursuant to 37 C.F.R. § 1.321(b)(2), Transkaryotic Therapies, Inc. hereby waives and disclaims any terminal portion of the term of the entire patent to be granted upon the

above-captioned application that may be subsequent to the expiration date of U.S. Patent Number 6,063,630. Transkaryotic Therapies, Inc. does not disclaim any terminal part of any patent granted on the above-captioned application prior to the expiration date of the full statutory term of U.S. Patent Number 6,063,630 in the event that it later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321, has all claims canceled by a reexamination certificate, or is otherwise terminated prior to expiration of its statutory term, except for the separation of legal title as stated above.

Pursuant to 37 C.F.R. §§ 1.321(b)(3) and 3.73(b), the undersigned attorney of record certifies that Transkaryotic Therapies, Inc., a corporation, is the assignee of the entire right, title, and interest in the above-captioned application by virtue of an assignment from the inventors. A copy of the assignment is enclosed.

The undersigned attorney of record has reviewed all the documents in the chain of title of the above-captioned application and, to the best of his knowledge and belief, title is in Transkaryotic Therapies, Inc.

Pursuant to 37 C.F.R. § 1.321(c)(3), this terminal disclaimer is being filed to obviate a double patenting rejection in the above-captioned patent application. Any patent granted on the application or any resulting patent that is subject to reexamination proceedings shall be enforceable only for and during such period that said patent is commonly owned with the patent that formed the basis for the rejection.

Pursuant to 37 C.F.R. § 1.321(b)(4), enclosed is a check in payment of \$55 for the fee set forth in 37 C.F.R. § 1.20(d). Please apply any additional charges or any credits to Deposit Account Number 03-2095.

Respectfully submitted,

Date:

June 26, 2001



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50010.007006 terminal disclaimer.doc

PATENT TRADEMARK OFFICE



21559

**T. D. INFORMAL MEMO DO NOT MAIL THIS MEMO TO APPLICANT**

DATE: July 4, 01  
 TO: EXAMINER Kelly  
 FROM: Sita Adams  
 PARALEGAL SPECIALIST

APPL. S.N.: 09 431,821  
 ART UNIT: 1631

SUBJECT: Decision on Terminal Disclaimer (T.D.) filed: 6/29/01

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next Office action to notify applicant of the T.D. If you disagree or have any questions, please see me or the Special Program Examiner. **THIS IS AN INFORMAL, INTERNAL MEMO ONLY. IT MUST NOT BE (1) MAILED TO APPLICANT OR (2) PLACED OF RECORD IN THE APPLICATION FILE.** When your action is complete, please initial, date and return this memo to me. **THANK YOU.**

- ☒ The T.D. is PROPER and has been recorded (see ¶14.23).
- ☐ The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below (see ¶14.24):
- ☐ The recording fee of \$ \_\_\_\_\_ has not been submitted nor is there any authorization in the application file for the use of a deposit account (see ¶14.26.07).
  - ☐ The T.D. does not satisfy Rule 321 in that the person who has signed the T.D. has not stated the extent of his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent (see ¶¶14.26 & 14.26.01).
  - ☐ The T.D. lacks the enforceable only during common ownership clause - needed to overcome a double patenting rejection, Rule 321(b) (see ¶14.27.01)
  - ☐ The T.D. is directed to a particular claim(s), which is not acceptable since "the disclaimer must be a terminal portion of the term of the entire patent to be granted." (MPEP 1490) (see ¶¶14.26 & 14.26.02).
  - ☐ The person who signed the T.D.:
    - ☐ is not an attorney "of record" (see ¶¶14.29 and 14.29.01).
    - ☐ has failed to state his/her capacity to sign for the business entity (see ¶14.28),
    - ☐ is not recognized as an officer of the assignee (see ¶¶14.29 & possibly 14.29.02).
  - ☐ No documentary evidence of a chain of title from the original inventor(s) to assignee has been submitted, nor is the reel and frame number specified as to where such evidence is recorded in the Office (see 37 CFR 3.73(b) and 1140 O.G. 72). **NOTE:** This documentary evidence or the specifying of the reel and frame number may be found in the T.D. or in a separate paper of record in the application (see ¶14.30).
  - ☐ The T.D. is not signed (see ¶¶14.26 & 14.26.03).
  - ☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting rejection is missing or incorrect (see ¶14.32).
  - ☐ The serial number of this application (or the number of the patent in reexam or reissue cases being disclaimed is missing or incorrect (see ¶¶14.26, 14.26.04 or 14.26.05).
  - ☐ The period disclaimed is incorrect or not specified (see ¶¶14.26, 14.27.02 or 14.27.03).
  - ☐ Other:
  - ☐ Suggestion to request refund (see ¶14.36). **NOTE:** If already authorized, credit refund to deposit account and do not check this item.

I have appropriately notified applicant(s) of the status of the Terminal Disclaimer filed in this case.

Ex. Initials: \_\_\_\_\_ Date: \_\_\_\_\_

RETURN THIS MEMO TO CPK2-8823.

(Rev. 5/98)

MPEP 1400-53

Rev. 1 Feb 2000